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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,287	06/08/2006	Patricia Kwong Phieu Burnell	PB60589USw	4976
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GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER EVOY, NICHOLAS LANE	
			ART UNIT 3768	PAPER NUMBER
			NOTIFICATION DATE 01/21/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,287	Applicant(s) BURNELL ET AL.	
	Examiner NICHOLAS L. EVOY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/8/06, 7/11/08 and 7/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996.

4. Regarding claims 1 and 11, Sexton teaches a method of improving lung delivery of pharmaceutical aerosols that includes: A method for predicting the tendency of inhaled particles to deposit within a first patient's throat when said particles are inhaled through an airway defined by said first patient's throat, said method comprising determining at least one internal physical parameter of said airway defined by the first patient's throat by means of acoustic imaging of the airway defined by the first patient's throat (Column 9, Lines 10-15); and matching said at least one internal physical parameter of the airway of the first patient's throat with a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of at least one other patient (Column 9, Lines 50-56), wherein said dataset also comprises pre-determined data relating to the tendency of said inhaled particles to

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deposit within said at least one other patient's throat (Column 11 Line 63 – Column 12 Line 7), and said matching thereby enables prediction of the tendency for the inhaled particles to deposit within the first patient's throat (Column 12, Lines 20-32). Sexton does not teach that the method referenced above could be performed using acoustic imaging for image and data acquisition. Czaja teaches using acoustic impulse reflection imaging to measure physical and geometric characteristics of a human airway (Page 504, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sexton and Czaja because the use of acoustic reflectance imaging would render Sexton's method of improving lung delivery of pharmaceutical agents more accurate, low cost, simpler and faster.

5. Regarding Claim 2, Sexton discloses an inhaler that acts as an aerosol drug delivery device during scanning (Column 10, Lines 20-29).

6. Regarding Claim 3, Sexton discloses an inhaler that acts as an aerosol drug delivery device that is capable of delivering multiple types of medicine (Column 12, Lines 7-19).

7. Regarding Claim 4, Czaja discloses using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2).

8. Regarding Claim 5, Sexton discloses a method of imaging that focuses on the throat, including the pharynx and oropharynx (Column 9, Lines 3-9).

9. Regarding Claim 6, Sexton discloses a method of imaging that can determine physical characteristics of a patient's throat such as geometric alignment, spatial

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configuration, and volumetric descriptors and as a result geometric and spatial orientations could be determined (Column 11, Lines 42-51).

10. Regarding Claim 7, Sexton discloses a method of imaging that makes use of a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of at least ten other patients (Column 9, Lines 50-56).

11. Regarding Claim 8, Sexton teaches the use of Magnetic Resonance Imaging (MRI) to collect internal physical parameters of the throat airway of at least one other patient (Column 11, Lines 40-67).

12. Claims 9 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996, in view of Stapleton et al, On the Suitability of e-Turbulence Modeling for Aerosol Dispersion on the Mouth and Throat: A Comparison with Experiment; Journal of Aerosol Science; 2000, Vol. 31, No. 6, pp 739-749.

14. Regarding Claim 9 and 12, Czaja et al and Sexton et al disclose a method for improving lung delivery of pharmaceutical aerosols and a method for measuring physical and geometric features of an airway using acoustic impulse reflection imaging as referenced above. Czaja and Sexton do not teach the use of a laboratory model or a specific geometric embodiment for the method. Stapleton et al disclose the use of a laboratory model that is a reconstruction of a previously measured throat (p. 741, Paragraph 7). Additionally, Stapleton et al disclose that the trachea is often modeled as a nearly cylindrical tube and that its length and diameter are well studied (p. 742,

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Paragraph 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al, Sexton et al and Stapleton et al because all of the inventions are in the field of imaging and modeling the dynamics of air movement in the throat and the construction of three dimensional, cylindrically-based laboratory models is a common method of conducting air movement research (Stapleton, Page 739, Paragraph 1-2).

15. Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996, in view of Zhou et al; Measurement of upper airway movement by acoustic reflection; Annals of Biomedical Engineering; 1995, Vol. 23, No. 1, pp. 85-94.

16. Regarding Claim 10, Czaja et al and Sexton et al disclose a method for improving lung delivery of pharmaceutical aerosols and a method for measuring physical and geometric features of an airway using acoustic impulse reflection imaging as referenced above. Czaja and Sexton do not teach the use of a curve-fitting method. Zhou et al disclose a curve fitting method used to aid in analysis of the geometric mapping of the throat through data collected with acoustic reflection imaging (Page 91). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al, Sexton et al and Zhou et al because all of the inventions are directed towards mapping of the geometric parameters of the throat, and a curve fitting method provides a way to give a continuous model of throat geometry for further experimentation and modeling.

Response to Arguments

17. Applicant's arguments filed 9/15/09 have been fully considered but they are not persuasive.

18. Regarding Applicant's argument that claims 1-8, 11, 13 and 14 are Not Obvious in view of the teachings of Sexton et al, US Patent Number 6,567,686 in view of Czaja et al: Applicant argues that Sexton in view of Czaja does not disclose a method of predicting the tendency of inhaled particles to deposit within a first patient's throat. Sexton discloses that the invention is related to "optimizing the delivery of pharmaceutical aerosol to targeted pulmonary sites" (Column 1, Lines 14-25) which involves statistical analysis and prediction of particle deposition based on mathematical constructs (Column 3, Lines 9-23). Because Sexton specifically references creating statistical models and assigning probabilities to certain events based on those models (i.e. predicting the tendency of inhaled particles to deposit on a patients throat), Applicant's arguments are not persuasive.

19. Applicant also argues that Sexton does not teach the use of a created database to predict the characteristics of new patients (that are not on the database). Sexton discloses that "of particular importance is the development of a device that would ensure targeted delivery of inhalation aerosols over a broad range of patient use patterns and anatomical makeup. Therefore, a method which can be used to acquire information regarding patient performance including the dynamic aspects of anatomical features and flow rate information could be instrumental in evolving device design and improving the precision of targeted pulmonary medication delivery. This disclosure

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utilizes imaging techniques to identify changes in physiological and geometric alignment of the oropharynx as a means to systemize drug doses received by patients" (Column 8, Lines 34-49). Sexton's disclosure is clearly directed to the development of a database that can be used to optimize the treatment of patients (that are not a part of the database) based on imaging data. Therefore, Sexton's invention would not be relevant to patient's that are already a part of the database. As a result, Applicant's arguments are not persuasive.

20. Applicant also argues that the substitution of the MRI (Sexton) with acoustic measurement (Czaja) would simply create a database of acoustic data, and such a database is no close to Applicant's claimed invention than Sexton in isolation. It is not clear from the disclosure of Sexton alone that acoustic reflectance imaging could be used to determine relevant anatomical characteristics and parameters claimed by Applicant. However, in view of the disclosure of Czaja, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use acoustic reflectance imaging in place of magnetic resonance imaging. As a result, Applicant's arguments are not persuasive.

21. Applicant also argues that the substitution of acoustic reflectance imaging method referenced in Czaja with the magnetic resonance imaging method referenced in Sexton would not have been obvious to one of ordinary skill in the art at the time of the invention. However, in their disclosure, Sexton only references SPECT as a possible alternative. Sexton additionally cites resolution and speed as the advantage of choosing MRI over SPECT. It appears that acoustic reflectance was not considered by Sexton,

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however in the disclosure of Czaja, it is disclosed that "the technique of acoustic rhinometry in the management of nasal obstruction has proved effective in the diagnosis of structural and mucosal abnormalities". Thus, according to Czaja acoustic reflectance imaging is ideal for making the types of measurements disclosed in Sexton, and subsequently would have been obvious to one of ordinary skill in the art to apply to the disclosure of Sexton. As a result, Applicant's arguments are not persuasive.

22. Regarding Applicant's argument that claim 11 recites assembling a database, determining at least one internal parameter of the airway, and matching at least one internal physical parameter of the airway defined by the first throat and is therefore non obvious: See response to arguments referenced above.

23. Regarding Applicant's argument concerning the rejection of Claim 2: See response to arguments referenced above. Although it would not be possible to use the acoustic rhinometer of Czaja simultaneously with an inhaler device, it is not required by Applicant's claims that they be used simultaneously. In response to applicant's argument that the use of the acoustic rhinometer of Czaja would prevent the use of an inhaler method for inhalation analysis, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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24. Regarding Applicant's argument concerning the rejection of Claim 8: Sexton alone discloses the use of MRI to collect data on throat geometry (Sexton, Abstract).

See response to arguments referenced above.

25. Regarding Applicant's argument that claims 9 and 12 are Not Obvious in view of the teachings of Sexton et al, US Patent Number 6,567,686 in view of Czaja et al, further in view of Stapleton et al: See response to arguments referenced above.

26. Regarding Applicant's argument that claim 10 is Not Obvious in view of the teachings of Sexton et al, US Patent Number 6,567,686 in view of Czaja et al, further in view of Zhou: See response to arguments referenced above.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NLE 12/22/09

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768